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## M E M O R A N D U M

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**TO:** INDEPENDENT CITIZENS' OVERSIGHT  
COMMITTEE (ICOC)

**FROM:** ELONA BAUM

**SUBJECT:** PROPOSED INTERIM REGULATIONS FOR THE IPSC  
BANKING INITIATIVE

**DATE:** MAY 18, 2012

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### **I. Background**

On December 8, 2011, CIRM's Governing Board ("ICOC") approved a concept plan for deriving and banking a comprehensive collection of disease specific human induced pluripotent stem cells (hiPSC). This effort will be funded through three separate Requests For Application (RFA) at a total cost of up to \$30M. These lines will serve as valuable tools in drug discovery and will be available to researchers worldwide. The Tissue Collection RFA No. 12-02 will fund clinicians and other scientists to identify, recruit and consent sufficient numbers of affected individuals within a disease population so as to effectively represent the disease's manifestations. Tissues will be collected and appropriate clinical, medical or diagnostic information, will be obtained to enable informed discovery of disease-related phenotypes and drug development activities using hiPSC-based models. These tissue samples will be provided (without charge) to the recipient of the CIRM hiPSC Derivation Award (RFA No. 12-03) for the production of the hiPSC lines. Once derived, characterized and released, the lines will be deposited in the CIRM hiPSC bank funded under RFA No. 12-04.

On May 8, 2012, the Intellectual Property and Industry Subcommittee ("IP Subcommittee") considered proposed interim regulations governing the hiPSC initiative which are substantially in the same form as those set forth in Exhibit A and which are summarized below. By a unanimous vote of the members present, the Subcommittee passed a motion recommending that the ICOC approve the proposed interim regulations. Since the IP Subcommittee meeting, the publication regulation was changed to include specific language adapted to address the unique nature of this funding initiative rather than incorporating CIRM's IP regulations (defined below) in whole. In addition, the prohibition on exclusive licensing will be set forth in a Deposit Agreement between the hiPSC Repository and CIRM.

### **II. Need for a Different Regulatory Scheme**

Under CIRM's current regulatory framework, awards are made in the form of a grant or a loan. If they are grants, CIRM's Intellectual Property and Revenue Sharing Regulations for For-Profit and Non-Profit Entities ("IP regulations") apply (as do other CIRM regulations such as the Grants Administration Policy). If they are in the form of a loan, then CIRM's Loan Administration Policy applies in addition to all provisions of the Intellectual Regulations, excluding Section 100608. The IP Regulations were drafted to address

conventional drug discovery activities and did not contemplate creation of a comprehensive repository of cell lines intended for broad distribution. As a result, the IP Regulations contain a number of provisions which are either not applicable or worse could impede the success of the hiPSC bank. For instance, IP Regulations permit the exclusive licensing of CIRM funded inventions and technology. This would be counter-productive to the goals of the hiPSC repository which are predicated on wide spread access. Similarly the IP Regulations include provisions relating to revenue sharing. However, these regulations would have no practical effect for RFA Numbers 12-02 and 12-03 as the grantees under these awards are not entitled to charge a fee for the materials they transfer pursuant to the award. With respect to the repository, it is important to have flexibility to negotiate in a Deposit Agreement any terms for revenue sharing as the primary objective is to ensure that the cell lines are made available at low cost while at the same time ensuring the repository is self-sustaining. Provisions in the IP Regulations that warrant inclusion, such as the requirement relating to acknowledgment of CIRM in publications resulting from us of the cell lines, will be included in the interim regulation.

### **III. Summary of Proposed Regulations**

The proposed interim regulations are attached and will provide, in pertinent part, the following:

- (i) Exempt from IP Regulations: Grantees will be exempt from the IP Regulations. These regulations are not consistent with the objectives of this initiative and if applied could actually be counter-productive.
- (ii) Ownership of the hiPSC Lines: Although the lines will be deposited in the repository, CIRM will be the actual owner of these cell lines. This permits CIRM to have complete control of this valuable resource and is consistent with the practice of NIH's Center for Regenerative Medicine which is also creating a repository for iPSC lines and derived materials. (Note: under the existing IP Regulations the Grantee would own the lines)
- (iii) Revenue Sharing and Pricing: As neither the awardee of the tissue generation RFA nor the awardee(s) of the derivation RFA will be permitted to sell the materials they create with CIRM funding, there will be no revenue sharing regulations which apply to them. The repository will be permitted to charge a reasonable fee for the lines. However, to ensure the repository can become self sustaining by the end of the project term, application of current revenue sharing provisions in the IP Regulations would likely be counter-productive. The Deposit Agreement between CIRM and the grantee of the repository RFA will set forth agreed to terms relating to revenue sharing and pricing.
- (iv) Publication: Researchers using lines from the CIRM funded repository would be required to acknowledge CIRM's funding.

### **EXHIBIT A**

Interim Regulations Governing Establishment of a Repository for Induced Pluripotent Stem Cells  
and Embryonic Stem Cells

## **1.0 Preface**

This interim regulation governs awards made under the three Requests For Application (RFA) Numbers 12-02, 12-03 and 12-04 that CIRM issued for the generation, banking and distribution of comprehensive collections of disease specific human induced pluripotent stem cells (hiPSC). These lines will serve as valuable tools in drug discovery and will be available to researchers worldwide.

## **2.0 Definitions**

- 2.1 hiPSC Repository** – The repository established pursuant to Request For Application 12-04.
- 2.2 hiPSC Repository RFAs** – Request For Application Numbers 12-02, 12-03 and 12-04 which provided funding for the creation of disease specific human induced pluripotent stem cells and a repository and distribution center for storing such cell lines.
- 2.2** All other capitalized and undefined terms shall have the meanings as set forth in CIRM’s Intellectual Property and Revenue Sharing for Non-Profit and For Profit Grantee regulations and CIRM’s Grants Administration Policy regulations.

## **3.0 Application of Intellectual Property and Revenue Sharing Regulations for Non-Profit and For Profit Grantees**

- 3.1** Awards made pursuant to the hiPSC Bank RFAs are exempt from CIRM’s entire Intellectual Property and Revenue Sharing for Non-Profit and For Profit Grantees regulations.

## **4.0 Application of Grant Administration Policy Regulations**

- 4.1** CIRM’s Grant Administration Policy regulations apply, in all respects, to awards made pursuant to the hiPSC Bank RFAs.

## **5.0 Application of The Scientific and Medical Accountability Standards**

- 5.1** CIRM’s Scientific and Medical Accountability Standards apply in all respects to awards made pursuant to the hiPSC Bank RFAs.

## **6.0 Ownership of Intellectual Property and Materials**

- 6.1 Background intellectual property:** All intellectual property of Grantees, Collaborators, and their subcontractors owned prior to engaging in the activities set forth in the hiPSC Repository RFAs shall remain the intellectual property of the Grantees, Collaborators and their subcontractors. CIRM shall have no rights to pre-existing intellectual property.
- 6.2 Ownership of the hiPSC lines:** CIRM shall own all hiPSC lines generated pursuant to the hiPSC Repository RFAs and shall retain all rights of such ownership including but not limited to rights to license or otherwise transfer.

**7.0 Revenue Sharing**

**7.1** CIRM may negotiate revenue sharing provisions with the hiPSC Repository taking into account the interest in ensuring that the hiPSC Repository becomes self sustaining.

**8.0 Publication**

**8.1** A researcher using a cell line obtained from the hiPSC Repository which was derived in whole or in part using CIRM funding shall, in any written publication and oral presentation, acknowledge CIRM's funding and identify by name the hiPSC Repository.